

## **REMARKS**

The above Amendments and these Remarks are in reply to the Office Action mailed April 17, 2006. No fee is due for the addition of any new claims.

Claims 1-6, 9-16, 18-19, 21, 23, 26-44 were pending in the Application prior to the outstanding Office Action. In the latest Office Action dated April 17, 2006, the Examiner rejected claims 1-6, 9-16, 18, 19, 21, 23, 26-40 and 44. Claim 21 has been amended.

## **AMENDMENTS TO THE SPECIFICATION**

The Applicant has amended the specification by importing claims 19 and 20 of the originally filed application, 10/684,668 (hereinafter '668), into the patent application (see paragraphs [0044]-[0045]). "Matter not in the original specification, claims or drawings is usually new matter". MPEP § 608.04(a). Here, the matter is in the original claims of the '668 application and therefore not new matter.

## **CLAIM REJECTIONS UNDER 35 U.S.C. § 112**

Claims 21 and 23 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

Claim 21 has been amended, wherein the reference to the first piece and the second piece are deleted from the claim.

The Examiner states "[r]egarding claim 23, the claimed configuration is ambiguous. The socket of the lower plate is parallel to the sagittal as shown in figure 1G not perpendicular" (page 4, sixth line from bottom). The Applicant reminds the Examiner that the specification states at

paragraph [0043] “[t]he foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art”.

A person having ordinary skill in the art would understand from the specification that it functionally makes no difference whether the socket in the lower implant is parallel with the sagittal plane as shown in Fig. 1G or perpendicular with the sagittal plane, provided that the upper implant is also modified such that the socket in the upper implant would be parallel to the sagittal plane. Thus the Examiner’s rejection incorrectly limits the breadth of the invention. The Examiner is reminded that during examination, the claims must be interpreted as broadly as their terms reasonably allow. MPEP 2111.01. Specifically, in Claim 23, reference is made to a sagittal plane. The sagittal plane is not ambiguous. Specifically, in Claim 23, there is only one plane perpendicular to the sagittal plane. The plane perpendicular to the sagittal plane is not ambiguous. Applicants respectfully request the Examiner to identify what term or terms in Claim 23 are ambiguous.

Claims 22 and 44 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Applicant has reimported Original Claims 19 and 20 into the specification at paragraphs [0044] and [0045]. Based on a comparison of paragraphs [0044] and [0045], a person having ordinary skill in the art would find apparent from the specification that a modification or variation would include the socket in the lower implant aligned perpendicular with the sagittal plane and the socket in the upper implant being parallel to the sagittal plane. “To satisfy the written description requirement, a patent specification must describe the claimed

invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention". MPEP 2163. The Applicant submits that the written description requirement is fulfilled as a comparison of paragraphs [0044] and [0045] gives sufficient detail such that one skilled in the art can reasonably conclude that the inventor understood that the socket in the lower implant can be either parallel or (in the case of claim 22) perpendicular to the sagittal plane.

Similarly, with regard to Claim 44, a comparison of paragraphs [0044] and [0045] gives sufficient detail such that one skilled in the art can reasonably conclude that the inventor understood that the socket in the upper implant can be parallel to the sagittal plane. The Applicant again requests a phone interview with the Examiner to clarify these issues.

In the absence of said phone interview, Applicants respectfully request that the Examiner withdraw the 35 USC 112 rejections.

#### **CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

Claims 1, 2, 4-6, 9-12, 14, 21, 23, 35-40, and 44 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Ferree (U.S. Publication No.: 2004/0106998) (hereinafter *Ferree*).

The Examiner considered the declaration by the inventor to be ineffective to overcome *Ferree*.

The Applicant herein supplies a new declaration by Steve Mitchell (hereafter Mitchell declaration). In the declaration, Mr. Steve Mitchell states that the declaration is made under 37 C.F.R. 1.131. (Mitchell declaration, ¶2). Mr. Mitchell states that he is an employee of St Francis Medical Technologies and specializes in spinal implant developments. (Mitchell declaration,

¶4). Mr. Mitchell, is the sole inventor of U.S. patent application 10/684,668. (Mitchell declaration, ¶5). Further, in the declaration, Mr. Mitchell declares under penalty of perjury that a prototype embodiment of the invention was shown on May, 2002 to an internal research and development team. (Mitchell declaration, ¶7). Mr. Mitchell declares Exhibits A and C are lateral anterior to posterior views of an artificial spinal model with the prototype inserted. (Mitchell declaration, ¶9). Mr. Mitchell declares Exhibits B and D are frontal anterior views of an artificial spinal model with the prototype inserted. (Mitchell declaration, ¶10). Mr. Mitchell declares that Exhibits A and C show the prototype implant described in the specification and shown in Figure 3 of the above application which incorporates the crossbar shown in Figures 2A-2D of the above application located between upper and lower plates inserted between two adjacent vertebrae of an artificial spinal model as represented in Figure 4 of the above application. (Mitchell declaration, ¶11).

Mr. Mitchell also indicates that the prototype had a first socket as claimed in Claim 1, element (a) and shown in Exhibit D. (Mitchell declaration, ¶13). Mr. Mitchell also indicates that the prototype had a second piece having a second socket as claimed in Claim 1, element (b) and shown in Exhibit D. (Mitchell declaration, ¶14). Mr. Mitchell also indicates that the prototype had a crossbar member as claimed in Claim 1, element (c) and shown in Exhibits A and D. (Mitchell declaration, ¶15). Mr. Mitchell also indicates that the crossbar had a first beam as claimed in Claim 1, element (d) and shown in Exhibit D. (Mitchell declaration, ¶16). Mr. Mitchell also indicates that crossbar had a second beam as claimed in Claim 1, element (e) and shown in Exhibit D. (Mitchell declaration, ¶17). Mr. Mitchell also indicates that length of the second beam of the crossbar was configured transversely to the length of the first beam as claimed in Claim 1, element (f) and shown in Exhibit D. (Mitchell declaration, ¶18). Mr.

Mitchell also indicates that the crossbar was partially received in the first socket and the second socket as claimed in Claim 1, element (g) and shown in Exhibit A. (Mitchell declaration, ¶19). Mr. Mitchell also indicates that the prototype was designed such that the crossbar did not fuse to the first piece as claimed in Claim 1, element (h) and shown in Exhibits A and C. (Mitchell declaration, ¶20). Mr. Mitchell also indicates that the first piece was capable of pivoting about the crossbar member to accommodate flexion, extension and lateral bending as claimed in Claim 1, element (j) and shown in Exhibits A and C. (Mitchell declaration, ¶21).

Mr. Mitchell indicates that the invention was made in this country. (Mitchell declaration, ¶25). The MPEP notes that “[f]or an actual reduction to practice, the invention ... need not be in a commercially satisfactory stage of development. If a device is so simple, and its purpose and efficacy so obvious, construction alone is sufficient to demonstrate workability.” Further, “...the evidence must establish a relationship between the subject matter, the test condition and the intended functional setting of the invention, but it is not required that all the conditions of all actual uses be duplicated, such as rain, snow, mud, dust and submersion in water.” MPEP 2138.05 II. Mr. Mitchell inserting the prototype in the model and in a cadaver establish a relationship between the implant, test conditions and the intended functional setting (Mitchell declaration, ¶22 and 23). Thus, Mr. Mitchell’s declaration is submitted as demonstrative evidence of construction and testing sufficient to establish actual reduction to practice by May 2002, prior to the effective date of *Ferree*.

### **CONCEPTION AND DUE DILIGENCE**

In the event that the Examiner finds that the current declaration supports conception of the claimed limitations of the invention prior to the publication date of *Ferree*, but not actual reduction to practice, then diligence is required just prior to the effective date of the reference

(October 4, 2002) until constructive reduction to practice (October 29, 2002) under 37 CFR 1.131. MPEP 715.07(a).

Applicant therefore addresses this eventuality. The declaration of Dr. Mitchell and the official USPTO record establish diligence through the following acts:

(i) Based on information or belief, between October 3, 2002 and October 29, 2002 the attorneys for St Francis Medical Technologies Inc. responsible for the patent application spent parts of eight days and in combination in excess of 25 hours preparing the application (Mitchell declaration, ¶24); and

(ii) the Examiner is requested to take official notice that the USPTO record of the application indicates that the provisional application upon which this application claims priority was filed on October 29, 2002.

As such the Applicants respectfully submit that they have established due diligence from before the publication date of *Ferree* until constructive reduction to practice.

The Applicant respectfully requests that the Examiner reconsider this rejection.

Claims 1, 2, 4-6, 9-12, 14, 21, 23, 35-40, and 44 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Wagner et al. (U.S. Patent No.: 6,706,070).

The Applicant supplies a new declaration from the inventor (as described in detail above). As such, the inventor is able to establish either actual reduction to practice of this invention prior to the effective date of *Ferree* or constructive reduction to practice and due diligence from before the publication date of *Ferree* until constructive reduction to practice.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the 102(e) rejections.

**CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

Claims 15-20 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ferree (U.S. Publication No.: 2004/0106998), in view of Marnay (WO 01/01893) (hereinafter *Marnay*).

Since *Ferree* is neither anticipatory nor prior art to the Applicants invention it is not available to be combined with *Marnay*.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the 103(a) rejections.

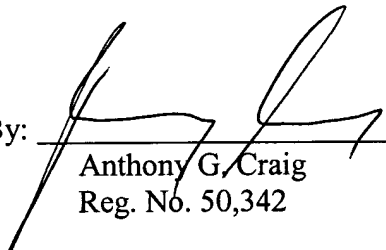
### CONCLUSION

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

No fee is believed due in connection with this paper. However, the Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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